UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

January 05, 2018

MEMORANDUM

Subject: Efficacy Review for Proxitane EQ Liquid Sanitizer, EPA Reg. No. 68660-4; DP Barcode: D443836; Submission #: 1009497; E-Sub # 22877.

From: Ibrahim Laniyan, Ph.D.
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Thru: Kristen Willis,
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Kristen Willis

To: Zeno Bain, PM33 / Terria Northern
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Solvay Chemicals, Inc
3737 Buffalo Speedway
Suite 800
Houston TX 77098

Formulation from the Label:

Active Ingredients	% by wt.
Hydrogen Peroxide	23.0 %
Peroxyacetic Acid	5.3 %
Other Ingredients:	71.7 %
Total	100.0 %

I. BACKGROUND

Product Description (as packaged, as applied): Liquid concentrate

Submission type: Label amendment

Currently registered efficacy claim(s): food and non-food contact surface sanitizer, and deodorizer for use on hard, non-porous surfaces

Requested action(s): 1) Add sanitizing claims for *Listeria monocytogenes* and *Salmonella typhimurium*; and, 2) Add disinfectant claims for *Staphylococcus aureus*, *Salmonella enterica*, and *Escherichia coli* on hard, nonporous surfaces.

Documents considered in this review:

- Letter from applicant to EPA September 25, 2017
- Application for Pesticide (EPA form 8570-1) dated September 25, 2017
- Certification with Respect to Citation of 1ata (EPA Form 8570-34) dated September 25, 2017
- Data Matrix (EPA Form 8570-35) dated September 25, 2017
- 6 efficacy studies (MRID 503420-01-503420-06)
- Proposed label dated November 13, 2017

II. PROPOSED DIRECTIONS FOR USE

DISINFECTION**
Proxitane® EQ Sanitizer can be used to disinfect hard, non-porous surfaces in the following areas: institutional and industrial facilities, laboratories, zoos, animal rearing and confinement facilities, farms, packing facilities, aquaculture facilities, food processing, handling and packaging facilities, transportation equipment and facilities, salons and barber shops.

** Proxitane® EQ Liquid Sanitizer has demonstrated efficacy as a disinfectant against *Staphylococcus aureus*, *Salmonella enterica*, and *Escherichia coli* when applied to pre-cleaned hard, nonporous surfaces, at a dosing rate of 0.55 to 0.75 fl. oz. per gallon of water (250-340 ppm of peroxyacetic acid and 1084-1478 ppm of hydrogen peroxide).

SANITIZATION*
Proxitane® EQ Liquid Sanitizer is for use in circulation cleaning and institutional/ industrial sanitizing of pre-cleaned hard nonporous food contact surfaces and equipment such as tanks, pipelines, evaporators, fillers, pasteurizers and aseptic equipment.

*This product has demonstrated greater than 99.999% reduction of *Staphylococcus aureus* and *Escherichia coli* in the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants study when applied to pre-cleaned surfaces at a dosing rate of 1.6 to 2.0 fl. oz. of Proxitane® EQ Liquid Sanitizer per 5 gallons of water (145-181 ppm of peroxyacetic acid and 631-788 ppm of hydrogen peroxide).

*This product has demonstrated greater than 99.999% reduction of *Listeria monocytogenes* and *Salmonella typhimurium* in the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants study when applied to pre-cleaned surfaces at a dosing rate of 1.7 to 2.0 fl. oz. of Proxitane® EQ Liquid Sanitizer per 5 gallons of water (154 -181 ppm of peroxyacetic acid and 670-788 ppm of hydrogen peroxide)

III. STUDY SUMMARIES

1.	MRID	503420-02	Study Completion Date:	June 27, 2017
Study Objective		Disinfectant		
Testing Lab; Lab Study ID		Accuratus Lab Services; A23283		
Test organism(s) ☐ 1 ☒ 2 ☐ 3 ☐ 4+		*Salmonella enterica* (ATCC 10708) and *Staphylococcus aureus* (ATCC 6538)		
Test Method		AOAC Use-Dilution Method		
Application Method		Liquid		
Test Substance Preparation	**Name/ID**	Proxitane EQ		
	Lots ☐ 1 ☐ 2 ☒ 3	LB010617CC-1, LB010617CC-2 and LB010617CC-3		
	Preparation	Tested concentration: LCL Dilution: 0.53 fl oz +1gallon Diluent: Sterile tap water (125, 215, and 155 ppm hardness)		
Soil load		No		
Carrier type, # per lot		Stainless steel penicylinders, 60		
Test conditions	**Contact time**	10 minutes	**Temp** 20.0 – 21.0 °C	**RH**
Neutralizer		Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.01% Catalase		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		**Protocol Amendments:** 1. Per Sponsor request, the dilution for the test substance Proxitane EQ lot LB010617CC-1, LB010617CC-2 and LB010617CC-3 will be updated to 0.53 fl oz/gallon defined as 0.53 fl oz+ 1 gallon of tap water. For clarity, in the Product Preparation section the sentence "Solvay will provide dilution instructions with the test samples" is no longer needed. 2. This protocol is amended to change Study Directors due to the departure of the original Study Director from Accuratus Lab Services. The Study Director has been changed from Dawn Anderson to Jamie Herzan.		

2.	MRID	503420-03	Study Completion Date:	June 28, 2017
Study Objective		Disinfectant		
Testing Lab; Lab Study ID		Accuratus Lab Services; A23282		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Escherichia coli* (ATCC 11229)		
Test Method		AOAC Use-Dilution Method		
Application Method		Liquid		
Test Substance Preparation	**Name/ID**	Proxitane EQ		
	Lots ☐ 1 ☒ 2 ☐ 3	LB010617CC-1 and LB010617CC-3		
	Preparation	Tested concentration: LCL Dilution: 0.53 fl oz + 1gallon Diluent: Sterile tap water (125 ppm hardness)		
Soil load		No		
Carrier type, # per lot		Stainless steel penicylinders, 10		
Test conditions	**Contact time**	10 minutes	**Temp** 20.0°C	**RH**
Neutralizer		Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.01% Catalase		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		**Protocol Amendments:** 1. At the request of the Sponsor and due to omission, the following updates and changes are to be made: 1. The following lots are to be used in testing: LB010617CC-1 and LB010617CC-3. 2. The test lots will be diluted as follows: 0.53 fl oz/gallon defined as 0.53 fl oz + 1 gallon sterile tap water. 3. On page 11 in the Test Substance Characterization & Stability Testing section, the following boxes should be checked: • "Physical & Chemical Characterization has been or will be		

	completed prior to efficacy testing" and 'Testing was or will be performed following 40 CFR Part 160 GLP regulations." • "[Stability testing] was or will be performed following 40 CFR Part 160 GLP regulations." 2. Due to a typographical error, the Protocol number on Amendment 1 should be changed to SVY01121616.UD.2. 3. The protocol is amended to change Study Directors due to the departure of the original Study Director from Accuratus Lab Services. The Study Director has been changed from Dawn Anderson to Amy Backler.

3.	**MRID**	503420-04	**Study Completion Date:**		May 31, 2017		
Study Objective		Sanitization					
Testing Lab; Lab Study ID		Accuratus Lab Services; A23239					
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Listeria monocytogenes* (A TCC 19117)					
Test Method		AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	Proxitane EQ					
	Lots **☐ 1 ☒ 2 ☐ 3**	LB010617CC-1 and LB010617CC-2					
	Preparation	Tested concentration: LCL Dilution: 0.33 fl oz + 1gallon Diluent: Sterile tap water (254 ppm hardness)					
Soil load		No					
# per lot		One flask					
Test conditions		**Contact time**	30 seconds	**Temp**	25°C	**RH**	
Neutralizer		Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.01% Catalase					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		**Protocol Amendments:** Per sponsor request, the protocol was amended to change the product preparation dilution to be tested to 0.33 fl oz/ gallon defined as 0.33 fl oz+ 1 gallon (9.76 ml test substance + 3785 ml diluent).					

4.	**MRID**	503420-05	**Study Completion Date:**		May 31, 2017		
Study Objective		Sanitization					
Testing Lab; Lab Study ID		Accuratus Lab Services; A23238					
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Salmonella enterica* (ATCC 10708)					
Test Method		AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	Proxitane EQ					
	Lots **☐ 1 ☒ 2 ☐ 3**	LB010617CC-2 and LB010617CC-3					
	Preparation	Tested concentration: LCL Dilution: 0.33 fl oz + 1gallon Diluent: Sterile tap water (129 ppm hardness)					
Soil load		No					
# per lot		One flask					
Test conditions		**Contact time**	30 seconds	**Temp**	25°C	**RH**	
Neutralizer		Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.01% Catalase					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		**Protocol Amendments:** Per sponsor request, the protocol was amended to change the product preparation dilution to be tested to 0.33 fl oz/ gallon defined as 0.33 fl oz+ 1 gallon (9.76 ml test substance + 3785 ml diluent).					

V. RESULTS

Disinfection – Bactericidal Efficacy

MRID (Test Date)	Organism	No. Exhibiting Growth/Total No. Tested			Average log_{10} CFU/Carrier
		Batch LB010617CC-1	Batch LB010617CC-2	Batch LB010617CC-3	
10 minute contact time, tap water, 0.53 oz/gallon					
503420-02 (5/12/17)	*Salmonella enterica* (ATCC 10708)	0/60	-	-	5.49
(5/15/17)		-	-	0/60	5.59
(5/16/17)		-	0/60	-	5.64
503420-02 (5/12/17)	*Staphylococcus aureus* (ATCC 6538)	0/60	-	-	6.84
(5/16/17)		-	0/60	-	6.93
(5/15/17)		-	-	0/60	6.73
503420-03	*Escherichia coli* (ATCC 11229)	0/10	-	0/10	4.23

Sanitization – Food Contact

MRID	Organism	Lot #	Test Results (Log_{10})	Population Control (Log_{10})	Reduction
3 seconds contact time, tap water, 0.33 oz/gallon					
503420-04	*Listeria monocytogenes* (ATCC 19117)	Batch LB010617CC-1	<0.00	7.96	>99.999
		Batch LB010617CC-2	<0.00		>99.999
503420-05	*Salmonella enterica* (ATCC 10708)	Batch LB010617CC-2	<0.00	7.71	>99.999
		Batch LB010617CC-3	<0.00		>99.999

VI. CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
503420-02, 503420-03	Disinfectant, bactericidal	Hard, non-porous surfaces	Liquid, 0.53 fl oz + 1gallon of water	10 minutes		Sterile tap water	• *Salmonella enterica* (ATCC 10708) • *Staphylococcus aureus* (ATCC 6538) • *Escherichia coli* (ATCC 11229)	Yes
503420-04, 503420-05	Food Contact Sanitization	Hard, non-porous surfaces	Liquid, 0.33 fl oz + 1gallon of water	30 seconds		Sterile purified water	• *Listeria monocytogenes* (ATCC 19117) • *Salmonella enterica* (ATCC 10708)	Yes

VII. LABEL RECOMMENDATIONS

Proposed Label dated November 13, 2017

1. The proposed label claims that the product, Proxitane EQ Liquid Sanitizer, (EPA Reg. No. 68660-4), is an effective disinfectant at 0.55 to 0.75 fl. oz. per gallon of water, against the following microorganisms on pre-cleaned, hard, non-porous surfaces for a 10-minute contact time at room temperature:

Salmonella enterica (ATCC 10708)
Staphylococcus aureus (ATCC 6538)
Escherichia coli (ATCC 11229)

These claims are acceptable as they are supported by the submitted data.

2. The proposed label claims that the product, Proxitane EQ Liquid Sanitizer, (EPA Reg. No. 68660-4), is an effective food contact sanitizer at 1.7 to 2.0 fl. oz. per 5 gallons of water, against *Listeria monocytogenes* (ATCC 19117) on pre-cleaned, hard, non-porous surfaces for a 1-minute contact time at room temperature:

These claims are acceptable as they are supported by the submitted data.

3. The proposed label claims that the product, Proxitane EQ Liquid Sanitizer, (EPA Reg. No. 68660-4), is an effective food contact sanitizer at 1.7 to 2.0 fl. oz. per 5 gallons of water, against *Salmonella typhimurium* on pre-cleaned, hard, non-porous surfaces for a 1-minute contact time at room temperature:

These claims are not acceptable. **The tested *Salmonella enterica* (ATCC 10708) is serovar Choleraesuis but not Typhimurium**. Registrant must replace all claims for *Salmonella typhimurium* with *Salmonella enterica* formerly *Salmonella choleraesuis*.

4. The applicant should make the following changes to the proposed label, as appropriate:

- List the tested microorganisms with the appropriate references (e.g. ATCC or other collection number).
- Remove all *Salmonella typhimurium* claims and replace with *Salmonella enterica* (ATCC 10708) or *Salmonella enterica* formerly *Salmonella choleraesuis*.
- On page 9, remove claims for “ELEVATED TEMPERATURE SANITIZING”, “SANITIZING NON-FOOD CONTACT PACKAGING EQUIPMENT”, and “FOAM SANITIZING NON-FOOD CONTACT SURFACES”. Efficacy data for those claims have not been submitted.
- On page 10 and 11, remove claim for” ENTRYWAY SANITIZING SYSTEMS”, “Harvesting and Field Equipment and Transportation Vehicle Sanitization”, and “TRACTOR TRAILER SANITIZATION”; non-food contact surface sanitization efficacy data were not submitted to support these claims.
- On page 13, under “INSTITUTIONAL AND INDUSTRIAL FACILITIES, LABORATORIES, RESEARCH FACILITIES, PACKAGING FACILITIES, PRODUCTION PLANTS”, remove medical device.
- On page 17, under “ANTIMICROBIAL RINSE”, remove all claims for spore forming bacteria (*B. coagulans, B. sporothermodurans, C. butyricum, A. acidoterrestris and G. stearothermophilus*). Non-public health claims for spore forming organisms are not permitted.